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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,754	10/04/2001	Anne-Marie Stomp	5051-337DVCT	5389

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/971,754	STOMP ET AL.
	Examiner Ashwin Mehta	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 October 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-70 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-70 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4, 6</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

1. In the paper submitted 04 October 2001, page 1, Applicants directed the cancellation of claims 1-37, 39, and 49-60. However, this amendment was not entered, as the original claims were numbered 38, 40-48, and 61-90.

Applicants are also notified that original claims 38, 40-48, and 61-90 were renumbered 1-40, to be in compliance with 37 CFR 1.126. New claims 61-90 were entered and re-numbered 41-70, again to be in compliance with 37 CFR 1.126. Claims 1-70 have been examined in this Office action.

Claim Objections

2. Claims 5, 12, 26, 33, 42, 56, and 63 are objected to because of the following informalities:

In claims 5 and 42, lines 3 and 4, all of the recitations of "a species of" should be deleted, as the claims already refer to particular species.

In claim 12, line 2; claim 26, lines 2 and 3; claim 33, line 2; claim 56, lines 3-4; claim 63, line 2: similar to claims 5 and 42, all of the recitations of "a species of" should be deleted.

Appropriate correction is required.

Claim Objections

3. Claims 11-40 and 41-70 are objected to under 37 CFR 1.75 (b) as being duplicate claims. Applicant is required to amend or cancel one set of the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-29 and 58-61 of U.S. Patent No. 6,040,498 ('498). Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims of the instant invention encompasses the scope of the claims of '498. The instant claims encompass stably transformed duckweed plants, cells, tissues, and tissue cultures that comprise the stably transformed tissues. The claims of '498 are drawn towards an Agrobacterium-mediated method for producing stably transforming duckweed, and stably transformed duckweed plant and tissues produced from the method. The duckweed species recited by the patented claims are the same as the species recited in the instant claims. Instantly claimed products may be made by any method, including the claimed method of '498. While the patent and the instant application share the same priority date, a terminal disclaimer is

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still necessary to avoid the problem of dual ownership of patents in the event that a patent issuing from the instant application ceases to be commonly owned with '498.

5. Claims 1-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-48, 59, and 60 of copending Application No. 10/273,974 ('974). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to stably transformed duckweed plants, cells, and tissues. The instant claims encompass stably transformed duckweed plants, cells, tissues, and tissue cultures that comprise the stably transformed tissues. The claims of '974 are drawn towards an stably transforming duckweed plants and tissues produced by particle bombardment. The duckweed species recited by the claims of '974 are the same as the species recited in the instant claims. Instantly claimed products may be made by any method, including the claimed method of '498. While the co-pending and the instant applications share the same priority date, a terminal disclaimer is still necessary to avoid the problem of dual ownership of patents in the event that patents issuing from the applications cease to be commonly owned.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 27, 28, 57, and 58 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 57 recite the limitation "said chimeric nucleic acid of interest" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim or parent claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any stably transformed duckweed plant, plant cell, or tissue comprising any heterologous nucleic acid of interest, or any chimeric nucleic acid of interest, incorporated in its genome.

The specification indicates that *Lemna gibba* fronds were subjected to particle bombardment with DNA comprising the GUS coding sequence (page 46, line 21 to page 47, line 12). The specification also indicates that *Lemna*, *Spirodela*, *Wolfia*, and *Wolfielda* fronds, Type I and Type II calli were transformed via *Agrobacterium*, and that transformed *Wolfia* fronds were regenerated into plants (page 47, line 15 to page 90, line 10). *Lemna* Type I callus was also

transformed via Agrobacterium with constructs carrying the human β -hemoglobin or a P450 oxidase coding sequences (page 90, line 13 to page 91, line 26).

However, the specification does not describe all stably transformed duckweed plants, plant cells, and tissues, carrying all heterologous or chimeric nucleotide sequences of interest. The structures of all such transgenic plants, cells, and tissues and their functions, are not described. While the specification describes particle bombardment- and Agrobacterium-mediated methods to introduce foreign DNA into duckweed frond and callus tissue, the methods themselves do not describe the structures and functions of all stably transformed duckweed plants, plant cells, and tissues. The stably transformed plants, plant cells, and tissues encompassed by the claims may comprise any type of transgene, which can confer any type of property, all of which are not described. The structures and functions of all such plants, plant cells, and tissues are not described. Further, the products encompassed by the claims include those that comprise any transgene, including those that have yet to be discovered. Such transgenes are obviously not described. Given the breadth of the claims encompassing all stably transformed duckweed plants, plant cells, and tissues, and lack of guidance as discussed above, the specification fails to provide an adequate written description of the products encompassed by the claims.

8. Claims 1-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stably transformed duckweed plants, plant cells, and tissues produced by Agrobacterium-mediated transformation, does not reasonably provide enablement for stably transformed duckweed plants, plant cells, and tissues produced by other methods. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any stably transformed duckweed plant, plant cell, or tissue comprising any heterologous nucleic acid of interest, or any chimeric nucleic acid of interest, incorporated in its genome.

The specification indicates that *Lemna gibba* fronds were subjected to particle bombardment with DNA comprising the GUS coding sequence (page 46, line 21 to page 47, line 12). The specification also indicates that *Lemna*, *Spirodela*, *Wolfia*, and *Wolfiella* fronds, Type I and Type II calli were transformed via *Agrobacterium*, and that transformed *Wolfia* fronds were regenerated into plants (page 47, line 15 to page 90, line 10). *Lemna* Type I callus was also transformed via *Agrobacterium* with constructs carrying the human β -hemoglobin or a P450 oxidase coding sequences (page 90, line 13 to page 91, line 26). The specification on pages 46-48 teaches the bombardment of *Lemna gibba* fronds and callus with microparticles coated with DNA comprising the GUS marker gene and an antibiotic resistance gene. Page 47, lines 8-12 indicates that GUS expressing cells were observed in the bombarded fronds. Page 48, lines 18-20, indicates that the selection of bombarded callus resistant to the selectable agent is continued for several weeks and that regeneration of transgenic fronds and plants is carried out as described in Example 42.

However, Example 42 describes regeneration from tissue transformed via *Agrobacterium*. It appears that the bombarded duckweed fronds and callus were transiently transformed as there is no indication in the specification that stably transformed cells, tissue, or

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plants were recovered when transformed by microparticle bombardment. That bombarded frond tissue displayed GUS foci is not an indication that the cells of the frond tissue were stably transformed. Confirmation of stable transformation requires several tests, including a tight correlation between physical (for example a Southern blot) and phenotypic data (for example an enzyme assay), a complete Southern analysis, data that discriminates between false positives and correct transformants, and molecular and genetic analysis of offspring, for example (Potrykus, Annu. Rev. Plant Physiol. Plant Mol. Biol. 1991. Vol. 42, pages 207-208). McCabe et al stress that optimization or maximization of transient activity does not necessarily result in optimal or any stable transformation, and believe that studies indicating transiently expressing cells and foci is meaningless and irrelevant to the final outcome particularly when the objective is recovery of transgenic plants (Plant Cell Tis. Org. Cult. 1993. Vol. 33, page 231). It is therefore unpredictable that the method taught in the specification can be used to produce stably transformed duckweed cells and plants. Given that methods used for transient transformation is not predictive of steps needed for stable transformation, and in the absence of further guidance, undue experimentation would be required by one skilled in the art to produce stably transformed duckweed cells and plants using the methods taught in the specification. Given the teaching of McCabe et al, it is especially important that the specification teach confirmation of stable transformation, as a transient gene expression assay system comprising microparticle bombardment of Lemna fronds has been known in the art for several years (Tobin et al., NATO ASI Series, 1991, Vol. 50, pages 167-179, see pages 172-174). It is suggested that a declaration be submitted by the inventors showing data that confirm the recovery of stably transformed

duckweed cells and plants using the microparticle bombardment methods taught in the specification.

The specification also does not enable one skilled in the art to produce any stably transformed duckweed plants, plant cells, or tissues by any other method. The transformation protocols discussed in the specification do not provide any information concerning other transformation methods. In the absence of further guidance, undue experimentation would be required by one skilled in the art to stably transform duckweed plants, cells, or tissues, other than via Agrobacterium. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims encompassing all stably transformed duckweed plants, cells, and tissues, comprising any heterologous or chimeric nucleic acid molecules of interest, produced by any method, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

9. Claims 1-70 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

April 7, 2003



Ashwin Mehta
Patent Examiner
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